



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,546	02/10/2004	James E. Van Hoeck	4002-3480	6689
52196	7590	11/30/2005		
KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER ISABELLA, DAVID J	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/775,546	HOECK ET AL.	
	Examiner	Art Unit	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 September 2005.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) 21-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20, 58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Currently, claim 1 has been amended to "a superior vertebral engaging face defined by said walls, said superior vertebral engaging face defining a first opening extending between said walls, said first opening in communication with said chamber; and an opposite vertebral engaging inferior face defined by said walls, said opposite vertebral engaging inferior face defining a second opening extending between said walls, said second opening in communication with said chamber". It is not clear how the walls define the openings when the chamber appears to define the openings. If applicant is relying on the thickness of the wall as defining the two engaging surfaces, applicant is invited to amend the claims to reflect such feature. Otherwise, it remains unclear as to how the chamber and the openings offer different physical features; and are they not, in fact, one and the same?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6,10,17-20,58 are rejected under 35 U.S.C. 102(b) as being anticipated by Michelson (5609635).

Michelson discloses a hollow spinal spacer for engagement between vertebrae, comprising: an anterior wall having a convexly curved anterior surface and opposite ends; a posterior wall having a flat posterior surface and opposite ends; two lateral walls, each integrally connected between said opposite ends of said anterior and posterior walls to define a chamber; and said walls further defining; a superior vertebral engaging face defining a first opening, the opening in communication with the chamber; and an opposite vertebral engaging inferior face defining a second opening, said second opening in communication with the chamber. See figures 1-7 of Michelson.

Contrary to applicant's assertion that the openings of Michelson do not meet the limitations as set forth in claim 1, Examiner maintains that Michelson still anticipates the claims as amended by applicant. Contrary to applicant's arguments, the claims are not limited to the interpretation that the openings are clearly defined by the walls of the implant. In fact, Michelson implant includes anterior, posterior and lateral walls defining inferior and superior surfaces (the collective walls delineate the planar two planar

Art Unit: 3738

surfaces). Therefor as broadly worded the claims as amended fails to distinguish over the implant of Michelson.

Claims 2-6, 17 & 18 see column 7, lines 15-32.

Claim 19, see threaded opening 126.

Claim 20 see figure 7.

Claim 58 fails to distinguish over the spacer of Michelson.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9,10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (5609635) as applied to claim 1 above, and further in view of Wozney, et al (5366875) and Heggeness (5514180).

Wozney et al teaches complexing the BMP with a carrier including polylactic acids and/or collagen for bone repair. To complex the BMP with a carrier to be placed in the chamber of Michelson so as to provide inductive or conductive new tissue formation into the implant for securing the implant between the adjacent vertebrae would have been obvious from the teachings of Wozney, et al. Heggeness et al (5514180) teaches the various species of BMP proteins that maybe used to facilitate

Art Unit: 3738

new bone tissue formation. The use of BMP 1 through BMP-7 are disclosed by Heggeness.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson et al (5609635) as applied to claim 10 above, and further in view of Silver et al (4703108).

The use of a matrix, in the form of a sponge, sheet and/or strip, is taught by Silver et al. To form the matrix in the form of a sheet to be inserted in the chamber of Michelson such that the matrix is more easily inserted inside the chamber would have been obvious from the teachings of Silver et al.

### ***Response to Arguments***

Applicant's arguments filed 9/21/2005 have been fully considered but they are not persuasive. See examiner's position in the body of the Office action.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

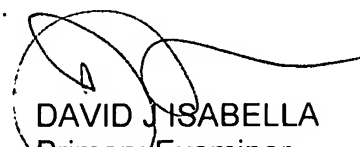
Art Unit: 3738

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J. ISABELLA  
Primary Examiner  
Art Unit 3738

DJI  
11/23/2005